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PCT/KR2003/002613

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Artcle 36 and Rule 70)

REC'D 21 MAR 2006
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Applicant's or agent's file reference OP04-1086	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. **PCT/KR2003/002613**	International filing date *(day/month/year)* **29 NOVEMBER 2003 (29.11.2003)**	Priority date *(day/month/year)*

International Patent Classification (IPC) or national classification and IPC

C12N 15/63(2006.01)i, A61K 38/10(2006.01)i, A61K 39/39(2006.01)i

Applicant

CHAE, Young-Jin et al

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
   - ☒ Box No. I Basis of the report
   - ☐ Box No. II Priority
   - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☐ Box No. IV Lack of unity of invention
   - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☐ Box No. VI Certain documents cited
   - ☐ Box No. VII Certain defects in the international application
   - ☐ Box No. VIII Certain observations on the international application

Date of submission of the demamd	Date of completion of this report
29 JUNE 2005 (29.06.2005)	22 FEBRUARY 2006 (22.02.2006)
Name and mailing address of the IPEA/KR Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer SHIN, Weon Hye Telephone No. 82-42-481-5591

Form PCT/IPEA/409 (cover sheet) (April 2005)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/KR2003/002613

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☒ This report is based on translations from the original language into the following language English, which is the language of a translation furnished for the purposes of:

   ☐ international search (under Rules 12.3 and 23.1(b))
   ☒ publication of the international application (under Rule 12.4)
   ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this reort as "originally filed" and are not annexed to this report):*

   ☒ the international application as originally filed/furnished

   ☐ the description:
   pages _____ as originally filed/furnished
   pages* _____ received by this Authority on _____
   pages* _____ received by this Authority on _____

   ☐ the claims:
   pages _____ as originally filed/furnished
   pages* _____ as amended (together with any statment) under Article 19
   pages* _____ received by this Authority on _____
   pages* _____ received by this Authority on _____

   ☐ the drawings:
   pages _____ as originally filed/furnished
   pages* _____ received by this Authority on _____
   pages* _____ received by this Authority on _____

   ☒ the sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:
   ☐ the description, pages _____
   ☐ the claims, Nos. _____
   ☐ the drawings, sheets _____
   ☐ the sequence listing *(specify)* : _____
   ☐ any table(s) related to sequence listing *(specify)* : _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   ☐ the description, pages _____
   ☐ the claims, Nos. _____
   ☐ the drawings, sheets _____
   ☐ the sequence listing *(specify)*: _____
   ☐ any table(s) related to sequence listing *(specify)* : _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/KR2003/002613

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-26	YES
	Claims	none	NO
Inventive step (IS)	Claims	none	YES
	Claims	1-26	NO
Industrial applicability (IA)	Claims	1-26	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Reference is made to the following documents from the International Search Report (ISR).
D1: US 5885579 A
D2: EP 1233066 A2

1. Novelty

Objective of the present invention is to provide a recombinant peptide vector comprising a leader peptide, linker DNAs and a DNA construct formed by operably linking expression control sequences with a gene encoding a fusion protein of the extracellular domain of CTLA4 and the Fc fragment of immunoglobulin (claim 1); a method for said vector (claim 23); and a composition for treating autoimmune diseases comprising the said vectors (claim 25).

D1 (see abstract; Fig 1, col.3, ll.34~40; col.4, l. 26 ~ col5., l. 15; col.9, ll.9~27; claims; and Example 2) relates to expression plasmids for a soluble [signal peptide-CTLA4-Ig] fusion protein, a method therefor and its use in treating immunoproliferative diseases including autoimmune diseases. D1 discloses in col.5, ll.12~13 that the extracellular domain of CTLA4 is an example of a soluble CTLA4 molecule. However, D1 differs from the present invention in that D1 does not indicate a leader peptide and linker DNAs that are linked to the gene encoding a CTLA4-Ig fusion protein.

D2 (see abstract; [0007]~[0024]; Fig 1; and claims) concerns a peptide vector, which does not have cell specificity. The vector comprises a leader peptide, a linker DNA and a desired gene.

- continued in Supplemental Box

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/KR2003/002613

Supplemental Box Relating to Sequence Listing

Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:

   a. type of material
   - [x] a sequence listing
   - [ ] table(s) related to the sequence listing

   b. format of material
   - [x] on paper
   - [x] in electronic form

   c. time of filing/furnishing
   - [x] contained in the international application as filed
   - [x] filed together with the international application in electronic form
   - [ ] furnished subsequently to this Authority for the purposes of search and/or examination
   - [ ] received by this Authority as an amendment* on _____

2. [ ] In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed of furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:

Box V

There is no prior art among the cited documents in ISR, which directly indicates or fairly suggests all constituents of the present invention.
Therefore, claims 1, 23 & 25 and their dependent claims 2-22, 24 & 26 are considered novel. Accordingly, claims 1-26 fulfill the criteria set forth in Article 33(2) PCT.

2. Inventive step

D2 notes in [0007] problems raised in prior arts such as viral vectors, which is the problem recognized in the present invention as well. The solution D2 takes is the same as the present invention except that the present invention limits the desired gene to the gene for the extracellular domain of CTLA4-Ig fusion protein. However, it is disclosed in D1.
Adopting the peptide vector of D2 for expression of a soluble CTLA4-Ig fusion protein is thus obvious to a person skilled in the art over prior arts. The acquired advantages of the mere combination of D1 & D2 are easily foreseen. Therefore, the subject matter of claims 1, 23 & 25 does not involve an inventive step. Dependent claims 2-22, 24 & 26 do not have any additional feature more than what is taught in prior arts including D1 & D2 and come within the scope of the customary practice readily followed by persons skilled in the art. Therefore, the subject matter of claims 2-22, 24 & 26 does not require exercising an inventive step.

Consequently, claims 1-26 do not fulfill the criteria set forth in Article 33(3) PCT.

3. Industrial applicability

There is no reason to negate the industrial applicability of this invention. Consequently, claims 1-26 appear to meet the requirements of Article 33(4) PCT.